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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,728	12/05/2003	George F. Kick	ONSET.002A	1724

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EXAMINER

SIMPSON, SARAH A

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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02/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,728	Applicant(s) KICK ET AL.	
	Examiner SARAH A. SIMPSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-29,47,49-51,60,62-64,72,74-76 and 83-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27-29,47,49-51,60,62-64,72,74-76 and 83-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the amendment filed 11/25/2008, amending claims 25, 47, 60 and 72, canceling claims 1-24, 26, 30-46, 48, 52-59, 61, 65-71, 73 and 77-82 and adding claims 83-90. Accordingly, claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-90 are pending and are present for examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. **Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86** rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Armstrong et al. (US 2002/0099431 A1)** in view of **Klein et al. (US 5,776,141)**.

Regarding claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86,

Armstrong discloses method of providing percutaneous access, said method comprising: inserting a guidewire (18) into or through a remote vessel ([0003]), percutaneously inserting an elongate tubular structure (12) having a first, smaller cross-sectional profile over the guidewire and into the renal collection system; expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 1, 1A-B), the tubular structure having a beveled tip (figs. 13A-C); inflating a balloon (15) by radial expansion with a balloon catheter (16) to expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile; and releasing the elongate tubular structure from a constraining tubular jacket (11), the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation or score line ((19); [0062]); and removing the balloon from the tubular structure following the expanding steps (figs. 13B-C). Armstrong further discloses the step of separating said constraint such as the tubular jacket by tearing it from the perforation or completely removing it from the tubular structure ([0068]). Although Armstrong does not specifically disclose that the device is inserted into the renal collection, the Examiner contends that either

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the areas of insertion disclosed by Armstrong (body conduits (20) such as vasculature [0061]) which include renal arteries meet this limitation, or in the alternative, it would have been obvious to have used it in such an area, as it was known to use similar expandable devices in renal arteries.

Armstrong fails to specifically disclose wherein the stent is deployed in the renal collection system.

However, Klein teaches a stent which is expanded via a balloon catheter in both the vascular system as well as in urethral cavities (column 3, lines 1-24).

Given the teachings of Klein, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Armstrong by placing the stent in the renal collection system, thereby, further utilize the device and method of Armstrong into the field of urology.

Claims 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fuqua (4,738,666)** in view of **Klein et al. (US 5,776,141)** and further in view of **Nishtala et al. (US 2001/0012950 A1)**.

Regarding claims 87-90, Fuqua discloses a method of providing percutaneous access, said method comprising: percutaneously inserting into or through the renal collection system (column 4, lines 24-26), an elongate tubular structure (14) having a first, folded, substantially continuous, smaller cross-sectional profile into the renal collection system, wherein in the first, folded, substantially continuous, smaller cross-sectional profile the elongate tubular body forms two longitudinally extending creased outer sections that lie on a perimeter of the folded tubular body and facing each other

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and two longitudinally extending creased inner sections that lie within the folded tubular body and face away from each other (figs. 1, 3); expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 5, 6); and inflating a balloon (38) to radially expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile (column 5, lines 63-64).

Fuqua fails to disclose wherein the elongate tubular structure is inserted over a guidewire and wherein the balloon catheter is removed from the tubular structure following the expanding steps.

However, Nishtala et al. teaches a guide wire (42) with a balloon catheter loaded into a sheath in the renal collection system, which is inflated to an appropriate pressure. This pressure provides radial force to dilate the tract and acts as an actuation device to the dilating elements. The balloon can then be removed for insertion of another, different sized balloon or to remove the dilator ([0004]; [0081]; [0082]).

Given the teachings of Nishtala et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of providing percutaneous access by inflating a balloon catheter to radially expand the tubular structure from a first smaller cross-sectional profile to a second, greater cross-sectional profile, and then removing the balloon following the expanding steps. Balloon catheters are commonly used and well known in the art to inflate structures such as tubes, sheaths, stents, etc. Balloons are preferable expanding devices as they are easy to use, cost effective, and allow a medical instrument to be expanded to a predetermined

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diameter. By having a separate balloon catheter guidewire system, the lumen through the tube of Fuqua could be increased in size, allowing additional medical instrumentation to be used.

Response to Arguments

Applicant's arguments with respect to claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-90 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731